MAR - 1 2012

510(k): K113037

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with
the requirements of 21 CFR 807.92.

1. Submitters Information:

Thu-Ha Duncan
PDI Works, LLC
2150 South Lee Highway
Cleveland, TN 37311
423-303-9981
PDIWorks@gmail.com
Prepared June 1, 2011

2. Device Identification:

Classification Name: Transcutaneous Nerve Stimulator.
Trade/Proprietary Name: Pain-Aid
Classification: Class II (21 CFR 882.5890)
Product Code: NUH, NYN

3. Identification of Predicate Devices:

The PDI Works Pain-Aid is of comparable type and substantially equivalent to the following predicate devices:

Endurance Therapeutics Therapeutic Massage Companion, K060846
Empi Select, K061650

4. Device Description:

The Pain-Aid is a transcutaneous electrical nerve stimulator for relief of muscular pain and sold without prescription. Key to its use are specially shaped electrodes that allow an untrained person to properly place them on the body.
The device consists of a microprocessor and associated components powered by a coin cell and housed in a small plastic case.
The controls for the device consist of three buttons: A power button which turns the device on and off, an intensity increase button, and an intensity decrease button. This simple user interface is further augmented by distinctive shapes to allow the user to identify the controls even if they cannot see the device.
Contact to the body is made through self-adhesive electrodes. Electrical connection from the device to the electrode is made directly through snaps on the device and the electrode; no leadwires are used. The electrodes are designed with both conductive surfaces combined into a single piece.

These electrodes are manufactured in various shapes to facilitate proper placement on the body.

5. Intended Use:

To be used for temporary relief of pain associated with sore and aching muscles in the upper and lower back, and upper and lower extremities due to strain from exercise or normal household and work activities. It is also intended to relieve chronic pain and pain due to arthritis.

6. Technological Characteristics

The table below summarizes the technological characteristics of the Pain-Aid And the predicate devices:

	Pain-Aid	Therapeutic Massage Companion	Empi Select
Intended Use	Muscular Pain Relief	Muscular Pain Relief	Muscular Pain Relief, Chronic and Arthritis Pain Relief
Output Waveform	Asymmetrical Biphasic	Asymmetrical Biphasic	Asymmetrical Biphasic
Technology / Control System	Microprocessor Control, Battery Powered	Microprocessor Control, Battery Powered	Microprocessor Control, Battery Powered
Patient Connection	Self-adhesive Electrodes	Self-adhesive Electrodes	Self-adhesive Electrodes
Safety	Limited Power, Simple User Interface	Limited Power	Prescription Device

Comparison of actual output under various loads and operating parameters shows no significant difference in the Pain-Aid and the predicate devices.

7. Conclusions:

The PDI Works Pain-Aid has the same intended use and similar technological characteristics as the cleared devices Therapeutic Massage Companion (K060846) and Empi Select (K061650). Additionally, testing of the devices has shown that any minor differences do not impact the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR - 1 2012

PDI Works, LLC
c/o Ms. Thu-Ha Duncan
President
2150 South Lee Highway
Cleveland, TN 37311

Re: K113037
Trade/Device Name: Pain-Aid
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Codes: NUH, NYN
Dated: February 7, 2012
Received: February 14, 2012

Dear Ms. Duncan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k113037

Device Name:

Pain-Aid

Indications for Use:

To be used for temporary relief of pain associated with sore and aching muscles in the upper and lower back, and upper and lower extremities due to strain from exercise or normal household and work activities.

To be used for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number k113037